UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,169	03/24/2005	Young-Min Lee	26689U	2581

20529 7590 12/15/2009

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
12/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,169	LEE ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12,15-17,22-25 and 29-37* is/are pending in the application.

4a) Of the above claim(s) *22-25* is/are withdrawn from consideration.

5)☒ Claim(s) *30 and 34* is/are allowed.

6)☒ Claim(s) *7-11,16,17,29,31,32 and 36* is/are rejected.

7)☒ Claim(s) *12,15,33 and 37* is/are objected to.

8)☒ Claim(s) *7-12,15-17,22-25 and 29-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 19, 2009 has been entered.

Response to Amendment

2. The amendments to the claims filed October 19, 2009 have been acknowledged and entered. Claims 7, 12 and 17 are currently amended.

Status of the Claims

3. Claims 7-12, 15-17, 22-25 and 29-37 are pending. Claims 1-6, 13-14, 18-21, 26-28 and 38 have been canceled. Claims 22-25 have been withdrawn from consideration. **Claims 7-12, 15-17 and 29-37 are under examination.**

Specification

4. The amendment to the Specification, filed October 19, 2009 has been entered.

The objection of the disclosure because Figure 3 comprised sequences which were not properly identified by sequence identifiers **is withdrawn** pursuant Applicants amendment to the specification.

Claim Objections

5. The objection of claim 12 because the claim contains sequences which were not properly identified by sequence identifiers **is withdrawn** pursuant Applicants amendment to the claim.

Response to Arguments

6. The rejection of claims 7-11, 18-19, 21 and 29 under 35 U.S.C. 103(a) as being unpatentable over Zhang et a. in view of Venugopal et al. **is withdrawn** pursuant Applicant's amendments to the claims and persuasive arguments.

New Claim Objection

7. Claim 10 is objected to because of the following informalities: The claim, designated as "previously presented", still contains amendment brackets and an underlined word from an amendment made of record March 14, 2008. Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, 32 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that Applicants submitted a copy of the Deposit and amended the specification to include the address of the depository. However, Applicants failed to state that all restrictions will be **"irrevocably removed"** upon the granting of a patent.

The appropriate accession numbers and required Deposit information critical or essential to the practice of the invention, as it relates to KCTC 10346BP and KCTC 10347BP, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification lacks sufficient deposit information for the "novel" KCTC 10346BP and KCTC 10347BP. Because this undefined plasmid is unknown, and therefore, publicly not available or can reproducibly isolated from nature without undue experimentation, a suitable deposit for patent purposes is required. See M.P.E.P. 608.01(p)(C).

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements. Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description. **Submission of a statement that all restriction will be "irrevocably removed" should obviate this rejection.**

9. Claims 7-11, 29, 31 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A review of the language of the claims indicates that these claims are drawn to a genus, i.e. a BAC vector encoding a full length cDNA of JEV, wherein the cDNA clone comprises a promoter. Claims 31 and 35 are drawn to a genus, i.e. pBAC^{SP6}/JVFLx/X*ba*l and pBAC^{T7}/JVFLx/X*ba*l.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* **SEQ ID NO:45 and SEQ ID NO:48**. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species. In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is **pBAC^{SP6}/JVFLx/X*ba*l and pBAC^{T7}/JVFLx/X*ba*l** or a BAC vector encoding a full length cDNA of JEV, wherein the cDNA clone comprises a promoter.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Amending claims 31 and 35 to include the SEQ ID NO's should obviate part of the rejection. In the alternative, amending the claims so claim 31 is dependent on claim 30 and claim 35 is dependent on claim 34 should obviate part of the rejection.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-11, 29, 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (2001) (made of record in Paper No. 20090407) in view of Almazán et al. (PNAS, May 2000, Vol. 97, No. 10, pp 5516-5521).

Zhang teaches a full length cDNA stable clone from Japanese encephalitis virus (JEV) (Abstract) (*as it relates to claim 7*). The cDNA has a T7 promoter at the 5' end and a "run-off"

transcript with vector sequences at either end (Abstract) (*as it relates to claim 8*). The full-length amplicon was cloned into a vector under the SP6 promoter (Abstract) (*as it relates to claim 9*). The RNA transcript was synthesized from the clone (page 174-175, connecting paragraph). Zhang teaches RNA transcripts were transfected into BHK-21 cells (page 175, 1st column, 1st paragraph). Zhang teaches Japanese encephalitis virus has short untranslated regions (nontranslated region) (*as it relates to claim 29*) (page 172, 1st column, 1st paragraph). Zhang teaches amplification of the full-length JEV genome by novel long RT-PCR protocol, transcription of infectious RNA directly from the amplicon and construction of a stable full-length JEV cDNA clone (page 173, 1st column, 2nd paragraph) (*as it relates to claims 7 and 10*). Zhang also teaches the transcript from the clone was non-infectious, however, the transcript from the amplicon of the clone was infectious (page 180, top of 2nd col.). Therefore Zhang teaches the limitations of claim 29 because the JEV genome (Flavivirus) inherently encodes a single polypeptide coding region. However Zhang does not teach the cDNA of JEV cloned into a BAC vector and is silent to whether the JEV cDNA clone is infectious.

Almazan teaches cDNA clones of single-stranded, positive-sense RNA viruses (JEV is a single-stranded RNA virus) which were cloned into a bacterial artificial chromosome (BAC) vector (p. 5516, Abstract and 1st paragraph) (*as it relates to claim 7*). Almazan teaches a cDNA clone encoding an infectious RNA virus genome (Abstract) (*as it relates to claim 7*). Almazan teaches removal of restriction endonuclease in the TGEV sequence generated a stable plasmid (p. 5518, 2nd column, 2nd full paragraph) (*as it relates to claim 10*). Almazan teaches BACs have been useful to clone large DNAs stably from a variety of complex genomic sources (p. 5516, 3rd paragraph). However Almazan does not teach a full length cDNA of JEV.

Since claims 31 and 35 are drawn to a generic BAC vector comprising a JEV cDNA and a promoter known in the art, Zhang and Almazan teach the limitations of these claims.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to clone the cDNA of JEV taught by Zhang into a BAC vector because Almazan teaches BACs have been useful to clone large DNAs stably with a reasonable expectation of success.

Response to Arguments

11. Applicants argue "nowhere do Zhang et al. describe that they produced an infectious cDNA clone of JEV. In response, Almazan teaches an infectious cDNA in the new grounds of rejection. Applicants argue "Venugopal et al. rather describe a baculovirus vector, which is different from a BAC vector as required by the presently claimed subject matter." In response, the BAC vector is taught by Almazan in the new rejection as set forth supra.

Allowable Subject Matter

12. Claims 12, 15, 33 & 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 30 and 34 are allowed.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M - F 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648
December 2, 2009

/Robert C. Hayes/, Ph.D.
Primary Examiner, Art Unit 1649